FEB 28

Section II

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K072211

Date	Feb 11, 2008
Submitter	Intuitive Surgical®, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Michael Yramategui Sr. Director, Regulatory & Quality Affairs Telephone: (408) 523 – 2145 ; Fax: (408) 523 - 1390 E-mail: mike.yramategui@intusurg.com
Subject Device	Trade Name(s): Intuitive Surgical® Instrument and Accessory Sterilization Trays Classification Name: Sterilization wrap containers, trays, cassettes & other Accessory (21CFR §880.6850) Common Name: Sterilization Cassettes, Instrument Tray, Sterilization Tray, Instrument Delivery System Device Class: Class II (KCT)
Predicate Devices	PolyVac Surgical Instrument Delivery System (K012105) PolyVac Inc. Paragon Medical Surgical Instrument Delivery System (K032119) Paragon Medical, Inc.

Predicate Devices (Cont.)	Olympus Sterilization Trays (K033222) Olympus Winter & Ibe
Device Description	Intuitive Surgical® Instrument and Accessory Sterilization Trays are intended only for use with Intuitive Surgical® EndoWrist Instruments and Intuitive Surgical Re-usable Accessories. These trays are used to enclose and hold the Instruments and Accessories in an organized manner during the sterilization process and subsequent storage and transportation. The trays are to be used with an approved sterilization wrap in order to maintain the sterility of the enclosed devices. The trays are different sizes of the same basic configuration: a rectangular base with latchable lids. The trays have perforations on the lid, bottom and sides to allow sterilant penetration. The bottom surface of the trays contains grooves custom made to fit and accommodate Intuitive Surgical® EndoWrist Instruments and Accessories. The grooves facilitate the Instruments and Accessory to be arranged in an organized manner when placed in the tray. The sterilization trays have been tested for use ONLY with the Intuitive Surgical® EndoWrist Instruments and Accessories for a sterilization cycle of Pre-Vac steam sterilization 132°C, 4min cycle with a 30 min dry time. This cycle parameter is similar to the current recommended sterilization cycle for the Intuitive Surgical® EndoWrist Instruments and Accessories.
Intended Use	Intuitive Surgical Instrument and Accessory Sterilization Trays are intended for the protection, organization and delivery to the surgical field of Intuitive Surgical EndoWrist Instruments and Intuitive Surgical Re-usable Accessories ONLY, as listed in Table 1 below.

TABLE 1: List of Compatible Devices

INTENDED CONTENT	DESCRIPTION
Intuitive Surgical EndoWrist Instruments	da Vinci & da Vinci S families of 8mm & 5mm EndoWrist Instruments
Intuitive Surgical Re-usable Accessories	da Vinci and da Vinci S families of 8mm & 5mm accessories including cannulae, obturators, cannula mount, sterile adapters etc

Intended Use (Cont.)

The trays are not intended to maintain sterility by themselves. They are designed to facilitate the pre-vacuum autoclave sterilization process when used in conjunction with a wrapping material (FDA cleared sterilization wrap). Wrapping materials are designed to allow air removal, steam penetration/evacuation and maintain the sterility of the internal components.

Autoclave Sterilization Parameter:

Cycle: Pre-vacuum
Temperature: 270-272°F (132-134°C)
Minimum Exposure Time: 4 mins
Minimum Dry Time: 30 mins

Table 2 provides description of 4 configurations of Intuitive Surgical Instrument and Accessory Sterilization Trays

TABLE 2: Intuitive Surgical Instrument and Accessory Sterilization Trays

TRAY NAME	**INTENDED CONTENT** ***(Intuitive Surgical EndoWrist Instruments and Intuitive Surgical Re-usable Accessories ONLY)***	**DIMENSION (Inches)** ***L x W x H***	**WEIGHT (Pounds)** ***UL: Unloaded*** ***FL: Fully Loaded***
Single Instrument Tray (P/N 400220)	One EndoWrist Instrument	24.1" x 9.7" x 3.5"	UL: 1lb FL: 2 lb
Instrument Tray (P/N 400221)	Eight EndoWrist Instruments	24.1" x 9.7" x 3.5"	UL: 1lb FL: 2 lb
Accessory Tray (P/N 400222)	Accessories	21.1" x 9.7" x 3.5"	UL: 5 lb FL: 13 lb
Procedure Tray (P/N 400223)	Eight EndoWrist Instruments & Accessories	24.1" x 9.7" x 5.5"	UL: 7 lb FL: 21 lb

Comparison to Predicate Device

Based on the comparison of design, technology, materials, manufacturing, performance, specifications, and method of use, the Intuitive Surgical® Instrument and Accessory Sterilization Trays are substantially equivalent to the identified 510(k) cleared predicate devices.

Technological Characteristics	The technological characteristics of the subject devices are equivalent to the predicate devices. The trays are made of standard medical grade materials are don't incorporate any new technological characteristics.
Performance Data	Design analysis and testing has been conducted to confirm that basic functional characteristics of the subject devices are substantially equivalent to the predicate devices cited, and that design output meets the design input requirements. Sterilization validation testing was performed to demonstrate successful sterilization of the Intuitive Surgical® EndoWrist Instruments and Intuitive Surgical Re-usable Accessories when enclosed in the sterilization trays and sterilized using a pre-vacuum cycle of 132°C, 4 mins with a 30 min dry time.
Conclusion	Based upon available technical information, intended use and performance information provided in this pre-market notification, the Intuitive Surgical® Instrument and Accessory Sterilization Trays described herein are substantially equivalent to current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Intuitive Surgical, Incorporated
C/O Mr. Morten S. Christensen
Responsible Third Party Official
Underwriters Laboratories, Incorporated
455 East Trimble Road
San Jose, California 95131-1230

Re: K072211
Trade/Device Name: Intuitive Surgical® Instrument and Accessory Sterilization Trays
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: February 14, 2008
Received: February 15, 2008

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

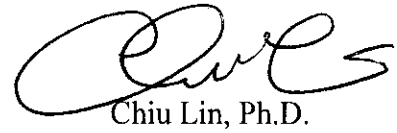
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072211

Device Name: Intuitive Surgical® Instrument and Accessory Sterilization Trays

Indications for Use:

Intuitive Surgical Instrument and Accessory Sterilization Trays are intended for the protection, organization and delivery to the surgical field of Intuitive Surgical EndoWrist instruments and Intuitive Surgical Re-usable Accessories ONLY, as listed in Table 1 below.

TABLE 1: List of Compatible Devices

INTENDED CONTENT	DESCRIPTION
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072211

Autoclave Sterilization Parameter:

Cycle: Pre-vacuum

Temperature: 270-272°F (132-134°C)

Minimum Exposure Time: 4 mins

Minimum Dry Time: 30 mins

Table 2 provides the description of the 4 configurations of the Intuitive Surgical Instrument and Accessory Sterilization Trays

TABLE 2: Intuitive Surgical Instrument and Accessory Sterilization Trays

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Prescription Use _____ AND/OR Over-The-Counter Use__X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of device Evaluation (ODE)